



U. S. ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2011-0954; FRL-9611-6]

Human Studies Review Board; Notification of a Public Meeting

AGENCY: U. S. Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The EPA Office of the Science Advisor announces a public meeting of the Human Studies Review Board to advise the Agency on the EPA scientific and ethical reviews of research with human subjects.

DATES: This public meeting will be held on January 26, 2012, from approximately 9:00 a.m. to approximately 5:30 p.m. Eastern Time. Comments may be submitted on or before Thursday, January 19, 2012.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2011-0954, by one of the following methods:

Internet: <http://www.regulations.gov>: Follow the online instructions for submitting comments.

Email: ORD.Docket@epa.gov.

Mail: The EPA Docket Center EPA/DC, ORD Docket, Mail code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, at 1301 Constitution Avenue NW, Washington, DC 20460. The hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566-1744 or email the ORD Docket at ord.docket@epa.gov

for instructions. Updates to Public Reading Room access are available on the website

<http://www.epa.gov/epahome/dockets.htm>.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2011-0954. The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any electronic storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to receive further information should contact Jim Downing at telephone number (202) 564-2468; fax: (202) 564-2070; email address: downing.jim@epa.gov or Lu-Ann Kleibacker on telephone number (202) 564-7189; fax (202)-564-2070; email address kleibacker.lu-ann@epa.gov; mailing address Environmental Protection Agency, Office of the Science Advisor Mail code 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA website at <http://www.epa.gov/osa/hsrb/>.

SUPPLEMENTARY INFORMATION:

Location: The meeting will be held at the EPA Conference Center – Lobby Level, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202.

Meeting access: Seating at the meeting will be on a first-come basis. To request accommodation of a disability, please contact the persons listed under **FOR FURTHER INFORMATION CONTACT** at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for providing public input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in Section I, “**Public Meeting**” under subsection D. “**How May I Participate in this Meeting?**” of this notice.

I. Public Meeting

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by the EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act. This notice might also be of special interest to participants of studies involving human subjects, or representatives of study participants or experts on community engagement. Since many entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using regulations.gov, you may access this *Federal Register* document electronically through the EPA Internet under the “Federal Register” listings at <http://www.epa.gov/fedrgstr/>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC, Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, at 1301 Constitution Avenue NW, Washington, DC 20460. The hours of operation are 8:30 am to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566-1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the website (<http://www.epa.gov/epahome/dockets.htm>). The Agency's position paper(s), charge/questions to the HSRB, and the meeting agenda will be available by the first week of January 2012. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, from the regulations.gov website and the EPA HSRB website at <http://www.epa.gov/osa/hsrb/>. For questions on document availability, or if you do not have access to the Internet, consult either Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**.

C. What Should I Consider as I Prepare My Comments for the EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data that you used to support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.

5. To ensure proper receipt by the EPA, be sure to identify the Docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

D. How May I Participate in this Meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by the EPA, it is imperative that you identify Docket ID number EPA-HQ-ORD-2011-0954 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments will be accepted up to Thursday, January 19, 2012. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via email) to Jim Downing or Lu-Ann Kleibacker, under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Thursday, January 19, 2012, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. Written comments. Submit your written comments prior to the meeting. For the Board to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of this meeting. If you

submit comments after this date, those comments will be provided to the Board members, but you should recognize that the HSRB members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the agency strongly encourages you to submit such comments no later than noon, Eastern Time, Thursday, January 19, 2012. You should submit your comments using the instructions in Section I., under subsection C., **“What Should I Consider as I Prepare My Comments for the EPA?”** In addition, the agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations to the EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA’s programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the Agency’s Science Advisor.

1. Topics for discussion. At its meeting on January 26, 2012, the EPA’s Human Studies Review Board will consider scientific and ethical issues surrounding these topics:

- a.** A new scenario design and associated protocol from the Agricultural Handler Exposure Task Force describing proposed research to measure dermal and inhalation exposure to workers who mix, load, and apply liquid pesticides with powered handgun equipment. The Agency requests the advice of the HSRB concerning whether, if it is revised as suggested in the EPA’s review and if it is performed as described, this research is likely to generate scientifically reliable data, useful for assessing the exposure of those who

mix, load, and apply liquid pesticides with powered handgun equipment, and to meet the applicable requirements of 40 CFR part 26, subparts K and L.

- b. The report of a completed scenario monograph and study report from the Antimicrobial Exposure Assessment Task Force II in which the dermal and inhalation exposure of professional janitorial workers was monitored as they applied a liquid antimicrobial pesticide product for indoor surface disinfecting using a pressurized aerosol can. The EPA seeks the advice of the HSRB on the scientific soundness of this completed research and on its appropriateness for use in estimating the exposure of professional janitorial workers who apply liquid antimicrobial pesticide products to indoor surfaces using pressurized aerosol cans, and on whether available information supports a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26.

- 2. Meeting minutes and reports.** Minutes of the meeting, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters, will be released within 90 calendar days of the meeting. Such minutes will be available at <http://www.epa.gov/osa/hsrb/> and <http://www.regulations.gov>. In addition, information regarding the Board's final meeting report, will be found at <http://www.epa.gov/osa/hsrb/> or from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: December 19, 2011.

Paul T. Anastas, EPA Science Advisor.

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